IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
(DALLAS DIVISION)

MILLARD ANDERSON and JENNIFER ANDERSON, Individually and as Next Friends of CLAYTON BOHART ANDERSON, a Minor, Plaintiffs,	§	
vs.	§	CASE NO. _____
ABBOTT LABORATORIES, Defendant.	§	JURY TRIAL DEMANDED

COMPLAINT

NOW COME Millard Anderson and Jennifer Anderson, individually, and as next friends of their son Clayton Bohart (Bo) Anderson, a minor, and file suit against Defendant, Abbott Laboratories, an Illinois corporation, and for cause of action would show the Court and Jury the following:

Nature of the Case

1. When your ten year old child is given a medication to treat a skin condition, you really do not expect him to contract leukemia or some other form of cancer because of it. However, that is just what happened to Millard and Jennifer Anderson's son Bo. Ten months after Bo's diagnosis with leukemia, Abbott finally implemented the **BLACK BOX** warning that the FDA required about the risk of pediatric leukemia. Because Abbott knew about this risk long before Bo Anderson

received his prescription for Humira, and failed to warn either physicians or patients about it in a timely and adequate way, it is liable for appropriate money damages under Texas law.

Parties

2. The minor Plaintiff Bo Anderson is a child who was born on October 27, 1997 in Victoria, Texas. Plaintiffs Millard "Andy" Anderson and Jennifer Anderson are his parents. All three are citizens of Texas.

3. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with headquarters in Abbott Park, Illinois. Abbott developed, manufactures, and markets a medication, the chemical name of which is "adalimumab" and the brand name of which is "Humira." It is expected that Abbott's counsel will accept a Rule 4 Notice of this suit so that formal service of process will not be required.

Jurisdiction and Venue

4. Jurisdiction is proper because Abbott Laboratories is an Illinois corporation, is headquartered in Abbott Park, Illinois, which conducts business throughout the State of Texas. Such business specifically includes the sale and distribution of pharmaceutical drugs, including Humira. The Andersons are residents of Dallas, Texas. The purchase and use of Humira on Bo Anderson occurred in Texas. There is diversity of citizenship between the parties in this case and the facts and injuries involved in this claim occurred in the Northern District of Texas.

Timeliness of Suit

5. Prior to the filing of this suit, Plaintiffs shared information with Abbott on an informal basis. Pursuant to an agreement between the parties, the statute of limitations was tolled. Therefore, this suit is timely.

Facts

This suit has been necessitated by the following facts:

Abbott's Blockbuster Drug

6. Humira, which was launched by Abbott in 2003, is the third drug in its "TNF blocker" biologic class to be approved by the FDA to treat rheumatoid arthritis and other autoimmune conditions. It is, in pharmacological jargon, a "blockbuster"[1] drug. Sales in 2009 – the year that Bo Anderson was diagnosed with leukemia and the year in which Abbott finally, at the FDA's behest, warned about this risk – were more than $5.5 billion.

7. Blockbuster drugs do not just happen. To sell more than a billion dollars' worth of any given medication, you have to persuade a lot of doctors to write a lot of prescriptions, and get a lot of patients to "ask their doctor" about a given drug.

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[1] A "blockbuster" drug is commonly defined either (a) as a drug that generates more than $1 billion in annual sales, or (b) "at its peak sales level, typically account for 20-30% of that company's total sales." Exhibit A, Stanford Graduate School of Business, ABBOTT LABORATORIES AND HUMIRA: LAUNCHING A BLOCKBUSTER DRUG, Case O1T-44 at p.2n.4. Condensed (6/25/2005)(written in cooperation with Abbott personnel)[hereinafter "ABBOTT BLOCKBUSTER."].

To make Humira a multi-billion dollar a year drug, Abbott adopted strategic marketing plans that focused more on their "message" than on the "data" about the safety and efficacy of Humira. As the Abbott Blockbuster article chronicles, to make Humira a multi-billion dollar medication, Abbott virtually remade the entire field of rheumatology. In doing so, Abbott misrepresented the efficacy of Humira and ignored or downplayed important safety data.

8. Abbott also utilized (a) extensive direct-to-consumer advertising, (b) multiple internet websites, and (c) direct-to-consumer programs designed to get patients to "self-diagnose" and ask their doctors for Humira. On information and belief, Abbott also promoted Humira for "off-label" use, like the prescription for psoriasis that young Bo Anderson received from his grandmother's rheumatologist.

Humira- The Potential Carcinogen

9. Humira is a drug that affects the human "tumor necrosis factor." With that name and mode of action, it does not take a rocket scientist or Nobel laureate medical researcher to figure out that it might have something to do with cancer.

10. Abbott knew well, prior to the launch of Humira, that the other two TNF-blockers, *i.e.,* Enbrel and Remicade, had been associated with lymphoma and other forms of cancer. Its clinical trial data also yielded a very significant epidemiological "signal" about this risk. And, once marketing began, the adverse event reports of various types of malignancies begin to pour in.

Abbott should have warned physicians and their patients about the risk of cancer. And, to protect children – whom it knew were receiving prescriptions "off-label" – Abbott should, of its own volition and on its own initiative, have warned specifically about the risk of pediatric leukemia before Bo Anderson ever received a prescription for this medication. But Abbott failed to warn.

11. On June 23, 2008, the FDA issued an Early Communication about the potential risk of TNF blocker-induced cancers in children. Its study focused on 30 cases of adolescent cancers. The FDA document stated that "Until the evaluation is completed, healthcare providers, parents, and caregivers should be aware of the possible risk of lymphoma and others cancers in children and young adults when deciding how to best treat these patients." Abbott, who has the legal responsibility for warning, should have immediately warned "healthcare providers, parents, and caregivers." But it did not do so. Rather, it sat idly by and waited for the FDA to act.

12. On August 4, 2009, the U.S. Food and Drug Administration mandated a **BLACK BOX** warning for all TNF blockers about the specific increased risk of lymphoma, adolescent leukemia, and other malignancies in children and adolescents. In so doing it exercised new statutory authority granted by the 2007 amendments to the FDCA. By this time there were at least 48 cases of children – 11 of them fatal – who had contracted cancer as a probable result of taking Humira or other TNF

blockers. In other words, 18 children contracted cancer and had it reported[2] to the FDA while Abbott and the other TNF Blocker manufacturers stalled and delayed warnings. The FDA action was a step in the right direction, but obviously, too little/too late for Bo Anderson.

13. Because of the FDA's actions, today, unlike then, physicians are warned by **BLACK BOX** warnings about two different types of cancers in children and adolescents. Today, *patients* receive an FDA-mandated Patient Medication Guide [PMG] that alerts them to the following:

> For children and adults taking TNF-blockers, including HUMIRA, the chances of getting cancer may increase. There have been cases of unusual cancers in children, teenagers, and young adults using TNF-blockers. . . . Some people receiving TNF blockers including HUMIRA developed a rare type of cancer called heptosplenic T-call lymphoma. This type of cancer often results in death. Most of these people were male teenagers or young men.

14. Prior to the **BLACK BOX** warning required by the FDA in 2009, no specific warning regarding Humira and leukemia was provided by Abbott. Abbott had a duty to keep abreast of the science, and to add a warning "as soon as" a reasonable association appeared. *See* 21 C.F.R. § 201.80 (e). But it breached this legal duty.

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[2] It is well established that only a small fraction of the real-world cases are reported to the FDA. The general rule of thumb is that somewhere between 1/10 or, worst case, 1/100 real-world cases are reported to the FDA.

An Innocent Child with Leukemia

15. At age 11, Bo Anderson was a typical, happy boy who enjoyed playing basketball, baseball, and football. Aside from a difficult case of psoriasis on his scalp and his trunk, he was a healthy boy. His dermatologist, Dr. David Thieberg, tried steroid creams and other treatments, but the patches of irritated skin on his scalp persisted.

16. Finally, Bo's grandmother, Mary Anderson, mentioned her grandson's psoriasis to her rheumatologist, Dr. Henry Townsend. Though Dr. Townsend does not generally treat children in his practice, he decided to see Bo. Dr. Townsend prescribed Humira in May 2008. On information and belief it is alleged that Abbott's sales representatives "detailed" Dr. Townsend and that Abbott encouraged him, in this and other ways, to prescribe Humira to treat psoriasis.[3] On information and belief it is further alleged that, between the FDA "Early Communication" on June 3, 2008, and December of 2008, Abbott's salesmen called on Dr. Townsend or others in his practice on numerous occasions and *failed* to do anything to alert them to this risk.

17. Consequently, in late December 2008, on a family vacation, Bo's parents, Andy and Jennifer Anderson noticed unusual bruising covering Bo's body. The family returned home and Jennifer quickly took him to the family doctor, Dr.

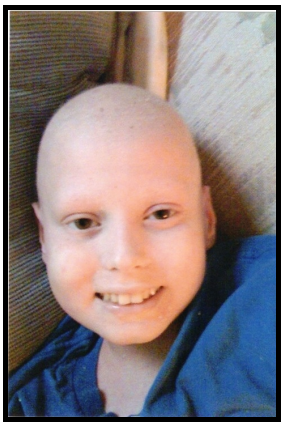
[3] There is considerable irony in this because Abbott knew that approximately 25% of the patients who are treated with Humira *develop* psoriasis or other serious skin problems *because* of Humira.

Angel Salazar. After running blood tests, Dr. Salazar advised the family to go to Children's Medical Center in Dallas immediately. Something was wrong. Horribly wrong.

18. On January 8, 2009, more than seven months *after* the FDA said that physicians and parents should be warned, and nearly ten months before Abbott finally issued a **BLACK BOX** warning regarding Humira-induced leukemia in pediatric and adolescent patients, Bo, at the age of 11, was diagnosed with T-cell acute lymphoblastic leukemia.

19. Instead of returning to school for his second semester of fifth grade, Bo stayed in the hospital. While his peers enjoyed playing sports, Bo was undergoing intense chemotherapy which made him violently ill, as well as multiple blood and platelet transfusions. To ensure that cancer did not spread, doctors also subjected Bo's brain to radiation - an absolutely horrific experience for him.

20. Pediatric leukemia can be a deadly medical condition. Treating oncologists aggressively attacked the cancer because leukemia carries such a high mortality risk. The following before/after Humira photos of Bo Anderson illustrate the devastation that Humira wreaked upon this innocent child's body:



21. Since his diagnosis in January 2009, Bo had to be hospitalized almost monthly for the first year for a variety of complications, with each stay being a week and often two. During one stay, he had to be rushed to ICU because his blood pressure dropped to dangerously low levels. He missed 75 days of school in his sixth grade year. Although Bo is now in remission, he must continue at least monthly chemo treatments. In addition, he must undergo spinal taps involving lumbar punctures and anesthesia every three months. In the words of his mother, "Bo's life has been taken away from him." Whenever his temperature rises above 101.5, he must return to the hospital. Even though Bo has handled leukemia bravely, his life has permanently changed. In addition, because of this illness and the associated treatment Bo was forced to undergo, this child now faces the very real potential for growth delays, learning difficulties, additional cancers and other physical or psychological disabilities. He continues to miss school due to treatments, and his

efforts this last school year to play the sports that he loves, basketball and baseball, were more than difficult for him.

When a potential side effect of a drug carries the risks of death, or treatments that approximate death, more than just the law demands Abbott's prudent action. Abbott's failure to timely warn of the known risk of pediatric leukemia threatened many patients. The Andersons now bring this claim for their son Bo and his damages. Bo and his parents will rely on the Jury to make an appropriate assessment of damages under the proper legal standards.

Causes of Action

The foregoing facts, incorporated herein by reference, give rise to the following theories of recovery under Texas law.

22. FIRST: STRICT LIABILITY. Abbott is liable to Bo and his parents under RESTATEMENT (SECOND) OF TORTS, §§ 402A and 402B, as adopted by the Courts and Legislature of the State of Texas. The Humira which was prescribed for him was "defective" and "unreasonably dangerous" under the law, and was a producing cause of Bo's leukemia and his family's economic and intangible damages. Suit is brought under this theory.

23. SECOND: NEGLIGENCE. Abbott failed to act as an "ordinarily prudent pharmaceutical company" should do under the "same or similar circumstances." This is negligence under Texas law. The specific acts of negligence

include Abbott's failure to warn, its misrepresentations, its over-promotion, and its negligent pharmacovigilance. Each was a proximate cause of Bo's leukemia and his family's economic and intangible damages. Suit is brought under this theory as well.

24. THIRD: BREACH OF WARRANTY. The Texas Supreme Court has held that a company that markets a "defective" product, as defined in the Texas Pattern Jury Instructions, has breached its implied warranties under the law. Abbott's product Humira was "defective" and that condition was a proximate cause of Bo's leukemia and his family's economic and intangible damages. Therefore, suit is brought under this theory as well.

Damages and Remedies

25. Plaintiffs sue to recover all elements of compensable damages under Texas law, including Bo's physical pain, mental anguish, disfigurement, physical incapacity, a/k/a "loss of capacity for the enjoyment of life", expense of hospitalization, and medical and nursing care and treatment both past and future. The damages claimed are in the millions of dollars. If Abbott requires a more definite *ad damnum* allegation Plaintiffs will be glad to accommodate via supplemental or amended pleading.

26. The evidence is both clear and convincing. Abbott made a conscious decision to expose Bo Anderson and other children to the risk of Humira-induced leukemia. Regardless of the legal label that one puts on this conduct, it is

reprehensible and worthy of significant punishment. Abbott is, therefore, liable for such damages as the Jury may assess, without regard to arbitrary "caps" that might be in force if the victim was someone older than Bo Anderson.

27. Abbott is also liable for pre-judgment interest and costs of court.

Jury Demand

28. Plaintiffs invoke their constitutional right to trial by jury.

Prayer for Relief

WHEREFORE, Plaintiffs pray that Defendant Abbott Laboratories be cited to appear and answer herein, and that, following trial, they recover such actual and punitive damages, prejudgment interest, costs of court, and other relief as is appropriate under the law.

Respectfully submitted,

PERDUE KIDD & VICKERY

/s/ Arnold Anderson Vickery
Texas Bar No. 20571800
Fred H. Shepherd
Texas Bar No. 24033056
1330 Post Oak Blvd., Suite 1800
Houston, TX 77056-3158
Telephone: 713-526-1100
Facsimile: 713-523-5939
Email: andy@justiceseekers.com
Email: fred@justiceseekers.com